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Little is known about what constitutes appropriate care for older women with breast cancer. Extending work begun as part of an National Cancer Institute-funded project, we are examining whether variations in care received by older women affect short-term psychosocial and clinical outcomes. Our specific aims are: 1) To describe patterns of adjuvant hormonal and chemotherapy in older women, and factors associated with receipt of these therapies; 2) To characterize and quantify the breast cancer-related care received by older women during the early years following diagnosis; and 3) To determine the effects of ongoing breast cancer care on patients' quality of life.

We are conducting a longitudinal observational study of a cohort of 350 women ≥ 55 years of age diagnosed with stage I and II breast cancer between October 1992 and December 1995 at five sites in Boston, Massachusetts. Women are interviewed annually to obtain information about health and personal characteristics. Medical record abstracts are performed annually to gather information about treatments received, tests performed, and disease recurrences. Descriptive and multivariate analytic techniques will be used to identify patient and provider characteristics associated with variations in care received and the effects of these variations on patients' quality of life.

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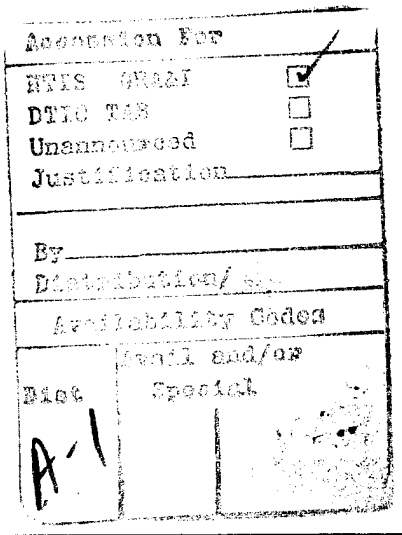

Stevie N. Kegler 8/23/95
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5. INTRODUCTION

Nature of the Problem

Little is known about what constitutes appropriate care for older women with breast cancer (1) because until recently, women ≥ 70 years of age were excluded from most clinical trials. It is perhaps not surprising, therefore, that there is considerable variation in how older women are treated (2-9). There are several reasons why careful longitudinal observational studies involving older women with breast cancer need to be performed. First, because of spiraling health care costs, Congress and third party payers are demanding that we determine, insofar as possible, what constitutes effective care for our patients. Although randomized clinical trials will continue to be the gold standard for assessing treatment efficacy, large numbers of older women are not likely to be enrolled in such clinical trials and those that are enrolled will not be representative of those cared for by most practicing physicians (1). Second, the variations in diagnostic evaluation and initial treatment that have been observed may or may not matter in terms of important short and long-term clinical outcomes (recurrence and mortality) and in terms of psychosocial outcomes (physical, social, and emotional function). Evidence linking variations in care received by older patients and variations in outcomes is lacking. While it is well-documented that older women are less likely to receive breast conserving surgery, follow-up radiation following breast conserving surgery, and axillary dissection, there is no convincing evidence that these differences adversely affect clinical outcomes (1). Although there are limited data regarding psychosocial outcomes, there is evidence to suggest that more extensive surgery is a risk factor for poor upper body function among older women, but not for poor emotional function (10). Because of the chronic nature of early stage breast cancer, what happens in terms of follow-up care (adjuvant therapy and surveillance testing) may have a greater effect on patients' well-being than initial treatment. Third, because the incidence of breast cancer is continuing to rise, because the incidence increases with age (11), appearing only to level off at about age 80-85 (12), and because the numbers of women 65 years of age are rapidly increasing, the absolute number of new breast cancer cases will continue to grow into the foreseeable future, as will the proportion of cases involving older women.

Background/Previous Studies

The current study is designed to identify determinants of variations in adjuvant hormonal/chemotherapy and follow-up care among older women with early stage breast cancer and the effects of these variations on health-related quality of life and breast cancer-specific function.

Evidence for Adjuvant Treatment Efficacy in Older Women:

Adjuvant Hormonal Therapy. Evidence supporting the use of tamoxifen in older women is relatively strong. Two clinical trials have focused specifically on older women and included women aged 65 to 84 with one or more positive axillary lymph nodes. Both studies found an increase in disease-free survival in the tamoxifen group, although with no effect on overall survival (13, 14). A meta-analysis of clinical trials conducted worldwide found a decrease in both recurrence and overall mortality rates among older women treated with tamoxifen. Of additional

importance, the magnitude of risk reduction, both in recurrence and mortality, was similar across postmenopausal age groups: 50-59, 60-69, and 70+ (15).

With respect to the issue of treatment duration, although a minimum of two years of treatment with tamoxifen is recommended, more prolonged treatment appears to be beneficial in delaying recurrence. Longer treatment may be beneficial in postmenopausal women because tamoxifen may prevent osteoporosis, lower levels of LDL cholesterol, and prevent contralateral breast cancer (15-18). Indeed, a recent report from the Scottish adjuvant tamoxifen trial suggests that tamoxifen given for at least five years reduces the risk of fatal myocardial infarction (19).

Although these data provide a strong scientific basis for clinical decision-making, no information is available about the treatment of older women with tamoxifen in community settings: patient and provider characteristics associated with its use, and the effects of treatment on patients' quality of life. The current study is addressing these issues.

Chemotherapy. The value of adjuvant chemotherapy with or without tamoxifen in postmenopausal women is controversial, and in women over 70 years of age, has not been well-studied. In the meta-analysis described above, adjuvant chemotherapy resulted in only a 10% reduction in the mortality of women aged 60-69, although recurrences were reduced significantly. There were only 274 women enrolled in chemotherapy trials who were $\geq$ 70 years of age, and in these, adjuvant chemotherapy did not appear beneficial (15). Clearly adjuvant chemotherapy cannot be considered standard treatment for postmenopausal women, especially those $\geq$ 70 years of age. It is possible, however, that adjuvant chemotherapy may be of benefit to subgroups of patients, especially those with aggressive disease. Because so little is known about the use of chemotherapy in older persons, the current project is addressing the following descriptive questions: 1) What proportion of older women, both with stage I and stage II breast cancer, currently receive adjuvant chemotherapy? and 2) What patient and physician characteristics are associated with receipt of chemotherapy?

Surveillance for Recurrence following Initial Therapy:

Although women are routinely followed by clinical examination and laboratory testing for evidence of recurrence, there is no evidence that this strategy results in earlier detection of recurrence or reduces mortality (20). Furthermore, case series evaluating the yield of various screening strategies have documented that most recurrences are detected either by patients themselves or by clinical examination (21-25). Only about 15% of recurrences are detected by surveillance testing which, in 1990 dollars amounts to an annual cost of about $1200/patient. No published studies have examined the costs and benefits, in human terms (either increasing anxiety or allaying fears), of surveillance testing, although a clinical trial evaluating these issues is reported to be in progress (25). Furthermore, none of the published studies have involved older women. Information about surveillance testing in older women is conspicuously lacking, including the types and frequency of testing and its impact on patient outcomes, particularly psychosocial outcomes. The current study is addressing the following questions: 1) How often are patients being seen and by which physicians during the early years following primary treatment? and 2) What are the types and frequency of surveillance tests and what are the effects of this testing on patient outcomes?

Summary: Given the national mandate to determine what constitutes effective health care and the fact that breast cancer is a disease primarily of older women (nearly half of newly diagnosed cases of breast cancer occur in women $\geq$ 65 years of age), we are conducting a longitudinal study of newly diagnosed older women with stage I and II disease: 1) to identify variations in follow-up

care, and 2) to link these variations to patient outcomes. In conjunction with limited clinical trial data, this will be valuable information to assist clinicians in medical decision-making. Together, these two types of data will be able to inform the development of guidelines for the care of older women with breast cancer.

Purpose of the Current Study

As described above, we are filling important gaps in knowledge by addressing the following **study questions** in our current study:

1. What patient and provider characteristics are associated with the receipt of hormonal and/or chemotherapy?
2. What are the effects of hormonal treatment on patients' quality of life?
3. What patient and provider characteristics are associated with the receipt of surveillance tests?
4. What are the effects of surveillance testing on patients' quality of life?

Our specific aims are:

1. To describe patterns of adjuvant hormonal and chemotherapy in older women, and factors associated with receipt of these therapies.
2. To characterize and quantify the breast cancer-related care received by older women during the early years following diagnosis.
3. To determine the effects of ongoing breast cancer care (adjuvant therapy and disease surveillance) on patients' quality of life.

Overview of Methods of Approach

As described in more detail below (**6. BODY**), we are studying a cohort of women ≥ 55 years of age with newly diagnosed early stage breast cancer over a 2-5 year time period. Initial telephone interviews are conducted at 3-5 months following initial definitive treatment, with subsequent interviews occurring approximately two years later, and annually thereafter. Medical records are abstracted, beginning at the time of diagnosis and continuing until project completion, or the development of metastatic disease or subject death. The medical record review covering the initial treatment period and the baseline interview are funded by the National Cancer Institute. The follow-up interviews and medical record reviews are funded under the current project by the US Army Medical Research and Development Command.

6. BODY

Overview and Summary of Progress of Parent Study Funded by the National Cancer Institute (CA57754)

Funding from the National Cancer Institute (NCI) is enabling us to enroll the cohort that is being followed longitudinally for the current project. Patients ≥ 55 years of age with newly diagnosed early stage breast cancer, being cared for at one of five hospitals with academic affiliation in Boston, Massachusetts, have been enrolled since January 1993. Our overall response

rate has been about 80%. Eligible patients are sent an introductory letter signed by their surgeon and a consent form approximately three months following initial surgical treatment. This is followed by a telephone call from our interviewer who further explains the study, answers questions, and obtains informed consent. Data are collected via a review of patients' surgical records, and a 30 minute computer-assisted telephone interview with consenting eligible patients. Data collected from medical records include: histology, stage, estrogen receptor status, surgery performed, additional therapies received, and medical comorbidities.

Our patient telephone interview includes questions about: general health-related quality of life (including a 10 item measure of physical function and a 5 item measure of emotional health, both from the SF-36), breast cancer-specific quality of life (including a 4 item measure of breast cancer-related worries), medical comorbidities, the treatment decision-making process, treatment priorities, perceptions of doctor-patient communication, and demographic characteristics.

Preliminary Results. One hundred seventy-five patients have been enrolled in the study thus far. Because subject accrual has been slower than anticipated, we have obtained a no-cost extension from the National Cancer Institute and will be enrolling new patients through March 31, 1996. Our final projected sample size is 325-350.

Descriptive data on the first 264 patients are presented in Tables 1-6. A little over half of our subjects are $\geq$ 65 years of age and most are white. Half are married; most of the remainder are widowed. The majority have a high school education or greater. Although a little over 40% report having hypertension, less than 20% report having chronic obstructive pulmonary disease, ischemic heart disease, or diabetes. The majority of patients have infiltrating ductal carcinoma and have stage I disease. Of interest, stage I patients tend to be slightly older than stage II patients (68.5 vs. 66.2 years for mean age), perhaps reflecting the increasing use of mammography in older women. In dramatic contrast to patterns of care observed elsewhere among older women with breast cancer, the majority of our patients undergo breast conserving surgery. The majority also undergo an axillary dissection. While there is no relationship between age and type of surgery (mastectomy vs. breast conserving surgery) in our study sample, there is a relationship between age and whether women who undergo breast conserving surgery receive a course of radiation therapy (Table 4). Women $\geq$ 75 years of age who undergo breast conserving surgery are significantly less likely to receive a course of radiation therapy than are women $<$ 75 years of age ($p=0.004$). Similarly, women $\geq$ 75 years of age are also significantly less likely to undergo axillary dissection (Table 5) than are their younger counterparts ($p=0.001$).

When asked about the helpfulness of breast cancer-related information received from a variety of sources, the information that was provided by their breast cancer physicians was rated as very or somewhat helpful by all responding patients. Written materials, both those provided by breast cancer physicians as well as those that patients obtained on their own, were also rated quite highly with respect to perceived helpfulness. Of less perceived helpfulness was information provided by friends and family, that from television specials, or that provided by the patient's family doctor, or the American Cancer Society.

We also asked patients about factors that were important in their decision-making. As can be seen, factors rated very important by almost all patients were two: 1) minimizing the possibility of recurrence, and 2) their doctors' recommendations. Although there was less consensus, also very important to the majority were quality of life after treatment and their family's opinion. In contrast, treatment-related factors were rated as not important at all by the majority of patients: 1) the effects of treatment on sexuality, 2) difficulty getting to and from treatments, and 3) the

effects of treatment on looks. Half or close to half also stated that what they would have to pay out-of-pocket, the length of treatment, discomfort and disability following surgery, other side effects of treatment such as nausea and fatigue, and other post-surgical problems were not important at all in their decision-making process.

In summary, we have found that in the academic practices we are studying in Boston, the majority of older women with newly diagnosed early stage breast cancer receive breast conserving surgery, regardless of age. Nonetheless, there remain age-related variations in primary treatment: the receipt of axillary dissection overall, and the receipt of radiation therapy among those undergoing breast conserving surgery. These age-related variations in the care of the oldest old are comparable to those reported by us and others previously, and do not appear to be changing with time. This may well reflect continued uncertainty about the value of these interventions in women $\geq$ 75 years of age. In addition, our patients reported that minimizing the risk of recurrence and their doctors' recommendations were the two most important considerations in their treatment decision-making.

Experimental Methods Used for Current Study

Preliminary Activities:

Institutional Review Board Approval: Institutional Review Board approvals were first obtained from each of the study sites. We received approval from Faulkner Hospital on July 31, 1994; from Boston University Medical Center on August 30, 1994;. from Boston City Hospital on September 2, 1994; from Beth Israel Hospital on November 8, 1994; and from New England Medical Center on December 13, 1994.

Computerized Tracking System: In preparation for the current study, the computerized tracking system, created in the Paradox environment from the ongoing NCI-funded breast cancer project, was modified to track the patient recruitment and contact processes for the current study. The system prepares subject contact letters and generates summary status reports as needed. In addition, the system provides a convenient gateway into the Computer Assisted Telephone Interviewing (CATI) System for patient interviews.

Instrument Development: The first subject interview for the current study was designed to include measures gathered in the baseline interview as part of the NCI study, as well as new measures and items that reflect the focus of the current study on adjuvant treatment and follow-up care. The new instrument was piloted with breast cancer patients from Boston University Medical Center who are not part of our study sample and revisions were made. A copy of this interview is included in Appendix A.

The medical record abstraction form was developed and pre-tested using blinded records of patients cared for at New England Medical Center. The focus of medical record data collection is on surveillance visits and test ordering by breast cancer surgeons, and medical and radiation oncologists caring for our study subjects. A copy of the medical record abstract form is included in Appendix B.

Although we had proposed initially to ask subjects to complete health care utilization diaries every six months, we have chosen two alternative approaches to minimize subject response burden and to maximize data quality and completeness. First, in the interview we ask about ambulatory care visits to primary and specialty care physicians in the prior year. Second, for

those patients receiving breast cancer-related care at locations other than our study sites, we ask for the names and addresses of providers in order to track and collect information about surveillance visits and testing. All breast cancer-related follow-up health care utilization is therefore captured by our medical record abstracting process.

Data Entry System: The first follow-up interview was transferred word-for-word to a database system. This system is designed to be used while the interviewer is conducting the interview over the telephone. As the subject answers the questions, the interviewer types the responses directly into the database system. The database system has various levels of built-in quality control checks. For example, range checks are enforced for almost every question in the instrument. If an out-of-range answer is entered, the system immediately informs the interviewer that the answer is out of range, and waits for an in-range answer. The only questions that do not enforce range checks are those defined as "free text response," where the subject is giving additional information that will be coded at a later time. In addition to range checking, the database system enforces skip patterns.

Training of Interviewer and Research Assistants: Our interviewer for the NCI study is conducting all interviews for the current study. Because she was familiar with the CATI system, her training focused on the new interview questions and their related medical terminology, as well as reviewing techniques to avoid leading or biasing patient responses.

Research assistants who are performing medical record abstractions for the parent project were trained to perform medical chart reviews using the follow-up medical abstract form. Training continued until inter-rater agreement was greater than 90%.

Study Implementation:

Subject Enrollment in the Current Study: Because we had trained staff to complete the preliminary activities described above, we were able to begin enrolling subjects in the current study in August 1994, shortly after funding began. Subjects enrolled in the NCI study are mailed a consent packet 20 months after their diagnosis date. This time interval was chosen because it was the shortest interval from initial diagnosis possible with the initiation of the US Army Research and Development Command funding.

Several days after the consent packet is sent, the interviewer calls the patient to review the purpose of the study, obtain informed consent, and answer questions. All initial interview for the current study are completed between 20 and 24 months after the patient's initial breast cancer diagnosis. As of July 21, 1995, 115 interviews have been completed. The non-participation rate is 18%. Ten patients could not be contacted because of changes in telephone numbers or addresses, or summer travel. An additional three patients have died and one was too ill to participate. Only 11 patients (8%) have actually refused to participate.

Medical record abstractions were begun in November 1994. Abstractions initially were recorded on paper data collection forms. Using project funded we have recently purchased a lap-top computer and a data entry system is being created This data entry system will have the same data quality checks as the interview data entry system. To maintain inter-rater reliability, a 20% random sample of charts will be reviewed by Dr. Silliman throughout the study. Abstractions for patients interviewed during the first project year will be completed by the end of September 1995.

Preliminary Results for Current Study:

As noted above, our first follow-up interview, approximately 20 months after the date of their original diagnosis, focuses on adjuvant therapy and follow-up care. Preliminary results reflect the 115 women who have completed their first follow-up interviews. Although we have experienced an 18% loss to follow-up, our follow-up sample is very similar to the full baseline sample. For example, at the time of diagnosis, 64% of the full sample were less than 70 years of age; in the follow-up sample, 68% of the women were less than 70 years of age at the time of diagnosis. Similarly, in the full baseline sample 65% of patients were diagnosed with stage I disease; in the follow-up sample 66% were diagnosed with stage I disease.

Overall, our subjects are functioning well at the time of their first interview, with essentially no change in mean physical or emotional function scores between baseline and follow-up. For example, in comparing physical function scores at baseline and follow-up (scores range from 0 to 100, with a score of 100 reflecting the highest possible score) for the 115 women, we have found that the mean score at baseline was 75; at follow-up it was 77. Similarly, the emotional health mean scores were the same at baseline and follow-up: 74.

Adjuvant Therapy. Sixty-eight percent of patients (n=78) reported that their physicians had recommended adjuvant tamoxifen therapy and 96% (n=75) of these women reported that they had actually begun tamoxifen therapy. Of the 75 patients who had taken tamoxifen at any time, 43 (57%) reported that they were experiencing side effects. Table 7 shows the type of side effects experienced by the women. The most common side effect reported was hot flashes, which were experienced by 84% of the women. Vaginitis and depression were two other side effects reported by an important minority of patients. Nonetheless, at the time of the interview, 64 patients (85%) reported that they were still taking tamoxifen.

Bivariate analyses demonstrate that although there is no significant difference between the proportion of stage I and stage II patients taking tamoxifen at the time of the interview, a higher proportion of stage II patients, as expected, were taking it: 61% of stage I patients; 74% of stage II patients. Within stage, similar proportions of younger ($\leq$ 69 years of age) and older ($>$ 70 years of age) women were taking tamoxifen. Among stage I patients, approximately 60% of both age groups reported that they were taking tamoxifen; among stage II patients, 72% of the younger group and 80% of the older group reported that they were taking tamoxifen. A larger proportion of younger women (74%) than older women (44%) reported that they were experiencing side effects from tamoxifen treatment. In spite of the fact that younger women were more likely to experience side effects, a similar proportion of younger and older women (84%; 86%) reported that they were still taking tamoxifen.

Only 25 (22%) patients reported that adjuvant chemotherapy was recommended, and all but one of these patients received treatment. All 24 patients who began chemotherapy reported that they experienced side effects. Tables 8 shows the type of sides effects experienced by these patients. The two most commonly reported side effects, each reported by 92% of the women, were hair loss and fatigue; 88% of women reported that they were troubled by nausea. However, only one patient did not complete a complete course of therapy. The vast majority (83%) of patients receiving chemotherapy were younger women. Two thirds of the patients receiving chemotherapy had stage II disease.

These data demonstrate that a physician's recommendation is the major determinant of older women's receipt of adjuvant therapy. However, the continuation of treatment is a more complex issue. Although the side effects experienced by women receiving chemotherapy were, on the whole, much more disruptive to their daily lives, the majority of women were willing to continue this short-term treatment. In contrast, 15% of the women who began tamoxifen treatment discontinued it at some point during the recommended two years of treatment. Side effects may be a partial explanation for why women discontinued treatment, but other possible explanations may include the length of treatment, perceived risks of ongoing treatment, and/or cost. The second follow-up interview will explore these issues in more detail.

Follow-up Care. Our subjects reported that they saw their family physicians about two times in the past year (mean=2.3), on average. Among patients who reported at least one visit, the mean number was slightly higher (mean=2.7). The mean number of visits to their breast cancer surgeon was 1.9; among those reporting at least one visit, the mean was 2.2. For all patients the mean number of visits to their medical oncologist was 1.7, while for patients reporting at least one visit it was 2.6. Finally, for radiation oncologist visits, the mean number of visits were 1.2 and 2.1 respectively. Across the entire sample, women reported making, on average, 4.6 visits to breast cancer specialists during the previous year.

Bivariate analyses by age (≤ 69 vs. > 70 years of age) and stage for all three types of breast cancer specialist visits identified few differences in patterns of care. Not surprisingly, younger women and those with stage II disease reported a greater number of medical oncology visits (1.9 vs. 1.3, $p=0.03$, and 2.5 vs. 1.3, $p=0.0006$, respectively). Stage II patients also reported a greater number of radiation oncology visits (1.3 vs. 0.8, $p=0.06$).

Approximately 50% of women reported that they felt calm before their breast cancer-related visits, while 30% reported that they did not. Similarly, 25% of women reported that they felt upset before their visit, while 63% stated that they did not. The vast majority of women reported that they felt good after a visit with their breast cancer specialist. Only 3% of women stated that they felt scared after a visit; 96% reported that they felt confident. Future analyses using medical record abstract data will allow us to determine whether it is abnormal test results, or referrals for further testing, that explain why a few patients feel upset after their visits and, conversely, whether the vast majority leave feeling better because they have been declared disease free.

Patients were also asked about how they were coping with feelings and concerns in their life that may be affected by their breast cancer. Most women, almost two years beyond their breast care diagnosis, reported that they feel they are doing well managing long-term life concerns. However, 18% of women reported that they were concerned about who would care for them if their condition deteriorated, and 13% reported that they were worried about recurrence. Nonetheless, only about 10% of women felt worried about their family's ability to manage if they became sicker. Analyses examining the relationship of factors such as stage and test results to patient concerns will help us to understand the context of these women's responses.

Plans for the 02 Project Year:

We will continue enrolling subjects participating in the NCI project until all have been approached. In addition, because of the rolling enrollment feature of the project, we have already begun to re-contact women interviewed in August 1994, since subsequent interviews will be

conducted annually. In order to lower the number of potential study participants lost to follow-up, we plan to contact family members who participated in the NCI study and enlist their help in locating subjects that we are not able to reach. As part of this process, we will make every effort to update the addresses and telephone numbers of those patients whom we were unable to contact for the first follow-up interview. If we are successful, we will attempt to enroll them in the current study, using the enrollment procedures described above.

The second follow-up interview has been developed and pre-tested. In addition to excluding questions that are no longer relevant for patients three years after diagnosis, new questions have been added that address issues related to long-term tamoxifen therapy and gynecological surveillance testing.

Medical record abstracting will continue throughout the 02 year using the form as originally developed. Each subject will have a medical record abstract form related to each year of follow-up after the completion of her initial definitive treatment. Medical abstracting will end if patients develop metastatic disease or die. If patients develop in-breast recurrence or contralateral disease, abstracting will be suspended until the second episode of definitive treatment has been completed.

For patients who have died, we will obtain copies of death certificates from the Massachusetts Department of Health to determine the cause of death.

7. CONCLUSIONS

Because the current project is as yet not complete, it is premature to speculate about project implications, or directions for future research.

8. REFERENCES

1. Silliman RA, Balducci L, Goodwin JS, Holmes FF, Leventhal EA. Breast cancer care in old age: what we know, don't know, and do. J Natl Cancer Inst 1993; 85:190-199.
2. Allen C, Cox EB, Manton KG, et al. Breast cancer in the elderly. Current patterns of care. J Am Geriatr Soc 1986; 34:637-642.
3. Samet J, Hunt WC, Key C, et al. Choice of cancer therapy varies with age of patient. JAMA 1986; 255:3385-3390.
4. Chu J, Diehr P, Feigl P, et al. The effect of age on the care of women with breast cancer in community hospitals. J Gerontol 1987; 42:185-190.
5. Greenfield S, Blanco DM, Elashoff RM, et al. Patterns of care related to age of breast cancer patients. JAMA 1987; 257:2766-2770.
6. Mann B, Samet J, Key C, et al. Changing treatment of breast cancer in New Mexico from 1969 through 1985. JAMA 1988; 259:3413-3417.
7. Silliman RA, Guadagnoli E, Weitberg AB, et al. Age as a predictor of diagnostic and initial treatment intensity in newly diagnosed breast cancer patients. J Gerontol 1989; 44:M46-50.
8. Bergman L, Dekker G, van Leeuwen FE, et al. The effect of age on treatment choice and survival in elderly breast cancer patients. Cancer 1991; 67:2227-2234.
9. Satariano ER, Swanson GM, Moll PP. Nonclinical factors associated with surgery received for treatment of early-stage breast cancer. Am J Public Health 1992; 82:195-198.

10. Satariano WA. Comorbidity and functional status in older women with breast cancer: Implications for screening, treatment, and prognosis. J Gerontol 1992; 47(Sp):24-31.
11. Boring CC, Squires TS, Tong T. Cancer statistics, 1993. Cancer J Clin 1993; 43:7-26.
12. Yancik R, Ries LG, Yates JW. Breast cancer in aging women. A population-based study of contrasts in stage, surgery, and survival. Cancer 1989; 63:976-981.
13. Castiglione M, Gelber RD, Goldhirsch A. Adjuvant systemic therapy for breast cancer in the elderly. Competing causes of mortality. J Clin Oncol 1990; 8:519-26.
14. Cummings FJ, Gray R, David TE, et al. Adjuvant tamoxifen vs. placebo in elderly women with node-positive breast cancer. Long term follow-up and causes of death. J Clin Oncol 1993; 11:29-35.
15. Early breast cancer trialists' collaborative group. Systemic treatment of early breast cancer by hormonal, cytotoxic, or immune therapy: 133 randomised trials involving 31 000 recurrences and 24 000 deaths among 75 000 women. Part 1. Lancet 1992; 339:1-15.
16. Fornander T, Rutqvist LE, Sjoberg HE, et al. Long term adjuvant tamoxifen in early breast cancer: effect on bone mineral density in postmenopausal women. J Clin Oncol 1990; 8:1019-24.
17. Love RR, Mazess RB, Barden HS, et al. Effects of tamoxifen on bone mineral density in postmenopausal women with breast cancer. N Engl J Med 1992; 326:852-56.
18. Love RR, Wiebe DA, Newcomb PA, et al. Effects of tamoxifen on cardiovascular risk factors in postmenopausal women. Ann Intern Med 1991; 115:860-64.
19. McDonald CC, Stewart HJ. Fatal myocardial infarction in the Scottish adjuvant tamoxifen trial. Br Med J 1991; 303:435-37.
20. Schapira DV, Urban N. A minimalist policy for breast cancer surveillance. JAMA 1991; 265:380-382.
21. Winchester DP, Sener SF, Khandekar JD, Oviedo MA, Cunningham MP,Caprini JA, et al. Symptomatology as an indicator of recurrent or metastatic breast cancer. Cancer 1979; 43:956-960.
22. Scanlon EF, Oviedo MA, Cunningham MP, Caprini JA, Khandekar JD, Cohen E, et al. Preoperative and follow-up procedures on patients with breast cancer. Cancer 1980; 46:977-979.
23. Pandya KJ, McFadden ET, Kalish LA, Tormey DC, Taylor SG, Falkson G. A retrospective study of earliest indicators of recurrence patients on Eastern Cooperative Oncology Group adjuvant chemotherapy trials for breast cancer. Cancer 1985; 55:202-205.
24. Marrazzo A, Solina G, Puccia V, Fiorentino E, Bazan P. Evaluation of routine follow-up after surgery for breast carcinoma. J Surg Oncol 1986; 32:179-181.
25. Zwaveling A, Albers GHR, Felthuis W, Hermans J. An evaluation of routine follow-up for detection of breast cancer recurrences. J Surg Oncol 1987; 34:194-197.

Table 1. Patient Demographics (n=264)	
Characteristic	n (%)
Age	
55-64	106 (43)
65-74	91 (36)
75+	52 (21)
Race	
White	248 (95)
African-American	8 (3)
Other minority	6 (2)
Marital Status	
Married	130 (50)
Widowed	85 (33)
Single	22 (8)
Divorced/Separated	24 (9)
Education	
< High school	47 (18)
High school graduate	90 (34)
> High school	124 (48)

Table 2. Patient Clinical Characteristics (n=264)	
Characteristic	n (%)
Comorbidity	
Hypertension	117 (44)
COPD	42 (16)
Ischemic heart disease	33 (13)
Diabetes	25 (10)
Breast Cancer	
Histology	
Infiltrating ductal	216 (86)
Infiltrating lobular	27 (11)
Other	9 (3)
Stage	
I	161 (65)
II	88 (35)

Table 3. Primary Tumor Management (n=264)	
	n (%)
Type of Surgery	
Breast conserving	194 (75)
Mastectomy	63 (25)
Axillary Dissection	
Yes	219 (85)
No	39 (15)

Table 4. Age and Radiation Therapy Follwing Breast Conserving Surgery (n=264)	
Age	n (%)
55-64	63 (91)
65-74	62 (91)
75+	23 (67)

Table 5. Age and Axillary Dissection (n=264)	
Age	n (%)
55-64	104 (98)
65-74	81 (89)
75+	25 (49)

Table 6. Patient Breast Cancer Treatment Decision-Making (n=264)	
	n (%)
Information sources perceived somewhat or very helpful in decision-making	
Breast cancer physicians or staff	260 (100)
Written materials from breast cancer physicians	219 (84)
Other written materials obtained by patient	179 (69)
Friends and family	136 (52)
Television	126 (49)
Family doctor	103 (40)
American Cancer Society	63 (24)
Factors very important in decision-making	
Minimizing recurrence	257 (99)
Doctors' recommendations	247 (96)
Quality of life after treatment	198 (77)
Family's opinion	133 (52)
Factors not important in decision-making	
Effects of treatment on sexuality	217 (84)
Difficulty getting to and from treatments	165 (64)
Effects of treatment on looks	160 (62)
What they would have to pay out-of-pocket	129 (50)
Length of treatment	122 (47)
Discomfort and disability following surgery	118 (46)
Other side effects of treatment	115 (44)
Other post-surgical problems	114 (44)

Table 7. Reported Side Effects of Tamoxifen Treatment (n=43)	
Type of Side Effect	n (%)
Hot flashes	36 (84)
Vaginitis	12 (28)
Depression	12 (28)
Nausea	5 (12)
Phlebitis	3 (7)
Edema	3 (7)
Other	15 (35)

Table 8. Reported Side Effects of Chemotherapy (n=24)	
Type of Side Effect	n (%)
Hair loss	22 (92)
Fatigue	22 (92)
Nausea	21 (88)
Depression	14 (58)
Flu Symptoms	12 (50)
Mouth Sores	6 (25)
Other	8 (30)

Appendix A

FOLLOW-UP PATIENT INTERVIEW
Phase I

Hello, my name is _____ . I work with Dr. Silliman at New England Medical Center and I'd like to ask you a few questions about how you have been doing since we spoke last year about your breast cancer treatment. The interview will take about twenty-five minutes. Is this a convenient time for you?

SECTION 1: OVERALL HEALTH

First, I'd like to begin with some questions about your health. Before we begin, I'd like you to get all of the medications that you take - both prescription and over-the-counter.

Although we would like you to answer every question, if there is one that you don't wish to answer, please let me know and we will go on to the next one.

1. In general, would you say that your health is:

(circle one)

Excellent 1
Very Good 2
Good 3
Fair 4
Poor 5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago 1
Somewhat better now than one year ago 2
About the same as one year ago 3
Somewhat worse than one year ago 4
Much worse than one year ago 5

Now I'm going to ask you about any difficulty you may have had using your arms because of your breast cancer treatment.

3. In the past four weeks, how difficult has it been for you to:

(circle one number on each line)

	Very Difficult	***Somewhat Difficult***	***Not Difficult***	***I Don't Do This***
Push or pull large objects like a living room chair?.....	1	2	3	4
Lift items <u>over</u> 10 pounds, like a heavy bag of groceries.....	1	2	3	4
Reach or extend your arms above shoulder level?.....	1	2	3	4

4. Are you bothered by <u>numbness and/or pain</u> in your axilla (armpit) as a result of your surgery?

(circle one)

No, not at all 0

Yes, somewhat 1

Yes, a lot 2

5. Are you bothered by <u>swelling or problems with your arm</u> as a result of your surgery?

(circle one)

No, not at all 0

Yes, somewhat 1

Yes, a lot 2

I'd next like to ask you some more general questions about your health and functioning.

6. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so how much?

(circle one number on each line)

	Yes, I Am LIMITED A Lot	***Yes, I Am LIMITED A Little***	***No, I Am Not LIMITED At All***
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.....	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	1	2	3
Lifting or carrying groceries.....	1	2	3
Climbing several flights of stairs.....	1	2	3
Climbing one flight of stairs.....	1	2	3
Bending, kneeling, or stooping.....	1	2	3
Walking more than a mile.....	1	2	3
Walking several blocks.....	1	2	3
Walking one block.....	1	2	3
Bathing or dressing yourself.....	1	2	3

7. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

(check one for each item)

	NO	YES
Cut down on the amount of time you spent on work or other activities	___	___
Accomplished less than you would like	___	___
Were limited in the kind of work or other activities	___	___
Had difficulty performing the work or other activities (for example, it took and extra effort)	___	___

8. **During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

(check one for each item)

	NO	YES
Cut down on the amount of time you spent on work or other activities	___	___
Accomplished less than you would like	___	___
Didn't do work or other activities as carefully as usual	___	___

9. **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

(circle one)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

10. How much bodily pain have you had during the past 4 weeks?

(circle one)

None at all 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe 6

11. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Extremely 5

For the next question I'd like you to take out the yellow card.

12. These questions are about how you feel and how things have been with you during the <u>past four weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

(circle one number on each line)

	ALL of the Time	***MOST of the Time***	***A GOOD BIT of the Time***	***SOME of the Time***	***A LITTLE of the Time***	***NONE of the Time***
Did you feel full of pep?.....	1	2	3	4	5	6
Have you been a very nervous person?.....	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?.....	1	2	3	4	5	6
Have you felt calm and peaceful?.....	1	2	3	4	5	6
Did you have a lot of energy.....	1	2	3	4	5	6
Have you felt downhearted and blue?.....	1	2	3	4	5	6
Did you feel worn out.....	1	2	3	4	5	6
Have you been a happy person.....	1	2	3	4	5	6
Did you feel tired?.....	1	2	3	4	5	6

13. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
None of the time 5

For the next question I'd like you to take out the blue card.

14. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	***Mostly True***	***Not Sure***	***Mostly False***	***Definitely False***
I seem to get sick a little easier than other people.....	1	2	3	4	5
I am as healthy as anybody I know.....	1	2	3	4	5
I expect my health to get worse.....	1	2	3	4	5
My health is excellent.....	1	2	3	4	5

15. Have you been told by a physician since you were diagnosed with breast cancer that you have any of the following problems with your breathing?

(check one for each item)

	NO	*YES*
Emphysema	___	___
Chronic bronchitis	___	___
Asthma	___	___
Other?_____	___	___

For the next question I'd like you to take out the yellow card.

16. During the <u>past four weeks</u>, how often have you felt short of breath:

(circle one for each item)

	ALL of the Time	*MOST of the Time*	*A GOOD BIT of the Time*	*SOME of the Time*	*A LITTLE of the Time*	*NONE of the Time*
When lying down flat	1	2	3	4	5	6
When sitting, resting	1	2	3	4	5	6
When walking less than one block	1	2	3	4	5	6
When climbing one flight of stairs	1	2	3	4	5	6
When climbing several flights of stairs	1	2	3	4	5	6

17. Have you been told by a physician since you were diagnosed with breast cancer that you have any of the following problems related to your heart or circulation?

(check one for each item)

	NO	YES
A heart attack	___	___
Congestive heart failure	___	___
High cholesterol	___	___
Angina	___	___
High blood pressure	___	___
Other?_____	___	___

18. During the past four weeks, how many times have you had any of the following problems related to your heart or circulation?

(circle one number on each line)

	More Than Once a Week	Almost Every Week	Once or Twice Only	NEVER
Chest pain or pressure when you exercise	1	2	3	4
Chest pain or pressure when resting	1	2	3	4
Ankles or legs that swell as the day goes on	1	2	3	4

19. Have you been told by a physician since you were diagnosed with breast cancer that you have any of the following problems?

(check one for each item)

	NO	YES
Stroke or TIA	___	___
Epilepsy or seizure disorder	___	___
Parkinson's Disease	___	___
Diabetes or high sugar	___	___
Thyroid problems, either underactive or overactive	___	___

20. **Have you developed any other new health conditions in the last year?**

(check one)

NO ***YES***

___ _____ → **19a. Please list these new health conditions.**

_____

_____

_____

_____

21. **Please tell me the names of all of the medicines that you take. (The medication name is usually found just below the dosage instructions, in the lower left corner).**

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

SECTION II: YOUR BREAST CANCER CARE

Now, I'd like to ask you some questions about your breast cancer care.

1. After you had your breast cancer surgery, did your doctors recommend that you receive radiation therapy (x-ray treatments)?

(circle one)

No..... 0 ⟶ **Go to Question 2**

Yes..... 1 ⟶ **Go to Question 1a**

1a. Did you receive radiation therapy?

(circle one)

No..... 0 ⟶ **Go to Question 2**

Yes..... 1 ⟶ **1b. Did you experience any side effects?**

(circle one)

No..... 0 ⟶ **Go to Question 1d**

Yes..... 1 ⟶ **1c. What were they?**

	YES	NO
1. Fatigue.....	___	___
2. Skin burn.....	___	___
3. Nausea	___	___
4. Shortness of breath	___	___
5. Other_____	___	___

1d. Did you complete your treatments?

(circle one)

Yes..... 0 ⟶ **Go to Question 2**

No..... 1 ⟶ **Why not?** _____

_____

_____

2. After you had your breast cancer surgery, did your doctors recommend that you receive tamoxifen (Nolvadex)?

(circle one)

No..... 0 ⟶ **Go to Question 3**

Yes..... 1 ⟶ **Go to Question 2a**

2a. Did you take it/are you taking it?

(circle one)

No..... 0 ⟶ **Go to Question 3**

Yes..... 1 ⟶ **2b. Have you experienced any side effects?**

(circle one)

No..... 0 ⟶ **Go to Question 2d**

Yes..... 1 ⟶ **2c. What were they?**

	YES	NO
1. Hot flashes.....	___	___
2. Vaginitis.....	___	___
3. Phlebitis.....	___	___
4. Depression.....	___	___
5. Nausea.....	___	___
6. Edema.....	___	___
7. Other_____	___	___

2d. Are you still taking tamoxifen?

(circle one)

Yes..... 0 ⟶ **Go to Question 3**

No..... 1 ⟶ **Why not?** _____

_____

_____

3. **After you had your breast cancer surgery, did your doctors recommend that you receive chemotherapy?**

(circle one)

No..... 0 ⟶ **Go to Question 4**

Yes..... 1 ⟶ **Go to Question 3a**

3a. Did you receive chemotherapy?

(circle one)

No..... 0 ⟶ **Go to Question 4**

Yes..... 1 ⟶ **3b. Did you experience any side effects?**

(circle one)

No..... 0 ⟶ **Go to Question 3d**

Yes..... 1 ⟶ **3c. What were they?**

	YES	NO
1. Nausea	___	___
2. Hair loss.....	___	___
3. Fatigue.....	___	___
4. Depression.....	___	___
5. Mouth sores.....	___	___
6. Flu-like symptoms..	___	___
7. Other_____	___	___

3d. Did you complete your treatments?

(circle one)

Yes..... 0 ⟶ **Go to Question 4**

No..... 1 ⟶ **Why not?** _____

_____

_____

4. **How many times a year do you see your:**

(enter number)

Type of doctor	
Primary care/family doctor.....	☐☐
Breast cancer surgeon.....	☐☐
Medical oncologist.....	☐☐
Radiation oncologist.....	☐☐
Other specialist.....	☐☐

5. **Who do you consider to be the breast cancer doctor in charge of your breast cancer care?**

_____

The following two questions ask about your feelings before and after a breast cancer check-up.

6. **<u>Before</u> I visit my breast cancer doctor I feel:**

(circle one number on each line)

	Strongly Agree	***Agree***	***So-so***	***Disagree***	***Strongly Disagree***
Calm.....	1	2	3	4	5
Scared.....	1	2	3	4	5
Upset.....	1	2	3	4	5
Confident.....	1	2	3	4	5
Supported.....	1	2	3	4	5
Under control.....	1	2	3	4	5
Depressed.....	1	2	3	4	5
Anxious.....	1	2	3	4	5

7. **<u>After</u> I visit my breast cancer doctor I feel:**

(circle one number on each line)

	Strongly Agree	***Agree***	***So-so***	***Disagree***	***Strongly Disagree***
Calm.....	1	2	3	4	5
Scared.....	1	2	3	4	5
Upset.....	1	2	3	4	5
Confident.....	1	2	3	4	5
Supported.....	1	2	3	4	5
Under control.....	1	2	3	4	5
Depressed.....	1	2	3	4	5
Anxious.....	1	2	3	4	5

8. **How is your breast cancer doctor at:**

(circle one number on each line)

	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Answering questions about your breast cancer and its treatment.....	1	2	3	4	5
Discussing treatment choices or options with you.....	1	2	3	4	5
Explaining each choice clearly.....	1	2	3	4	5
Adjusting or modifying treatment plans to fit your needs.....	1	2	3	4	5
Explaining why she/he is ordering lab tests, x-rays, etc..	1	2	3	4	5
Helping you deal with your concerns about your breast cancer.....	1	2	3	4	5

9. **How would you rate the quality of the information given to you by your doctor?**

(circle one)

Excellent 1
Very good 2
Good 3
Fair 4
Poor 5

10. **Compared to other doctors who have cared for you, how would you rate your breast cancer doctor's:**

(circle one number on each line)

	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Personal manner - for example, courtesy, respect sensitivity, friendliness.....	1	2	3	4	5
Communication skills - for example, listening carefully, answering questions, giving clear explanations.....	1	2	3	4	5
Technical skills - for example, thoroughness, carefulness, competence.....	1	2	3	4	5
Overall care.....	1	2	3	4	5

11. **Thinking about your discussions with your breast cancer doctor, how would you rate <u>your abilities</u> at:**

(circle one number on each line)

	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Asking questions about your breast cancer and it's treatment.....	1	2	3	4	5
Telling your doctor about your concerns about your breast cancer (for example, fear, anxiety).....	1	2	3	4	5
Getting your doctor to explain treatment options and their side effects.....	1	2	3	4	5
Getting your doctor to take your preferences into account when treatment decisions are made.....	1	2	3	4	5
Getting your doctor to explain why she/he is ordering laboratory tests.....	1	2	3	4	5

Now I'd like to ask you some questions about how having breast cancer has affected your life.

12. How well do <u>you feel you</u> are doing with each of the following:

(circle one number for each line)

	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Dealing with feelings such as anger, fear, grief, and anxiety.....	1	2	3	4	5
Worries about your family's ability to manage if you get sicker.....	1	2	3	4	5
Worries about who will take care of you if you get sicker.....	1	2	3	4	5
Worries about recurrence of the cancer.....	1	2	3	4	5

For the next question I'd like you to take out the green card.

13. How satisfied are you with:

(circle one number for each line)

	Very Satisfied	***Somewhat Satisfied***	***So-so***	***Not too Satisfied***	***Not Satisfied At All***
The overall appearance of your breast or scar.....	1	2	3	4	5
Your overall body appearance.....	1	2	3	4	5

14. Overall, how helpful has your family been in your:

(circle one number for each line)

	Very Helpful	*Somewhat Helpful*	*Not too Helpful*	*Not Helpful At All*
Adjusting to a different body image.....	1	2	3	4
Dealing with concerns about your sexuality.....	1	2	3	4
Dealing with feelings such as anger, fear, grief, and anxiety.....	1	2	3	4
Dealing with concerns about about the breast cancer coming back.....	1	2	3	4

For the next question I'd like you to take out the pink card.

Now I'd like to ask you about some issues that other people with breast cancer have said are important. While some will sound like others that you have already answered, they are a little different. For each statement, please indicate how true it has been for you in the past 7 days.

15. During the past 7 days:

(circle one number on each line)

	Not At All True	***A Little Bit True***	***Somewhat True***	***Quite A Bit True***	***Very Much True***
I have a lack of energy.....	1	2	3	4	5
I have nausea.....	1	2	3	4	5
I have trouble meeting the needs of my family.....	1	2	3	4	5
I have pain.....	1	2	3	4	5
I am bothered by side effects of treatment.....	1	2	3	4	5
In general, I feel sick.....	1	2	3	4	5
I am forced to spend time in bed...	1	2	3	4	5

16. During the past 7 days:

(circle one number on each line)

	Not At All True	***A Little Bit True***	***Somewhat True***	***Quite A Bit True***	***Very Much True***
I am able to work (include work in home).....	1	2	3	4	5
My work (include work at home) is fulfilling.....	1	2	3	4	5
I am able to enjoy life "in the moment".....	1	2	3	4	5
I have accepted my illness.....	1	2	3	4	5
I am sleeping well.....	1	2	3	4	5
I am enjoying my usual leisure pursuits.....	1	2	3	4	5
I am content with the quality of my life right now.....	1	2	3	4	5

17. During the past 7 days:

(circle one number on each line)

	Not At All True	***A Little Bit True***	***Somewhat True***	***Quite A Bit True***	***Very Much True***
I have been short of breath.....	1	2	3	4	5
I am self-conscious about the way I dress.....	1	2	3	4	5
My arms are swollen or tender.....	1	2	3	4	5
I feel sexually attractive.....	1	2	3	4	5
I have been bothered by hair loss.....	1	2	3	4	5
I worry about the risk of cancer in other family members.....	1	2	3	4	5
I worry about the effect of stress on my illness.....	1	2	3	4	5
I am bothered by a change in weight.....	1	2	3	4	5
I am able to feel like a woman.....	1	2	3	4	5

SECTION III: PERSONAL CHARACTERISTICS

The final questions are about yourself:

1. Are you currently:

(circle one)

Married 1
Not married, living with someone 2
Divorced 3
Widowed 4
Separated 5
Single (never married) 6
Other?_____ 7
(please specify)

2. Beside yourself, how many people live in your household?

(enter number) ____ ____ people

3. Are you now working at a paying job?

No Yes

____ ____ → **3a. Are you working full-time or part-time?**

(circle one)

Full-time (35 or more hours per week) ..... 1 → **Go to Question 6**

Working part-time, because of my health ..... 2 → **Go to Question 6**

Working part-time, for reasons other than health ..... 3 → **Go to Question 6**

On sick leave or leave of absence ..... 4 → **Go to Question 6**

Go to Question 4

4. **Does your health keep you from working at a paying job?**

(check one)

No ___ Yes ___ → **If yes, go to Question 6**

5. **Are you now:**

(circle one)

Retired 1

Laid-off or unemployed 2

A full-time homemaker 3

Other?_____ 4
(please specify)

For the next question I'd like you to take out the gray card.

6. **Which of the categories best describe your total annual combined household income from all sources?**

(circle one)

Less than $5,000 0

$5,000 to $9,999 1

$10,000 to $14,999 2

$15,000 to $19,999 3

$20,000 to $29,999 4

$30,000 to $39,999 5

$40,000 to $49,999 6

$50,000 and up 7

Not sure 8

Refused 9

Appendix B

Patient ID Number:_____ Follow-up: 1 2 3

Initial therapy completion date: _____/_____/_____

Recurrence tx completion date: _____/_____/_____

Notes:

SURVEILLANCE FOLLOWING INITIAL THERAPY

Surveillance Testing: Surgeon

Date of visit	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Surveillance type										
Patient History										
Physical Exam										
Mammogram										
Liver Function Studies										
(CBC) Complete Blood Count										
(CEA) Carcinoembryonic Antigens										
Chest X-rays										
Skeletal surveys										
Bone scan										
Liver scan										

Surveillance Testing: Radiation Oncologist

Date of visit	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Surveillance type										
Patient History										
Physical Exam										
Mammogram										
Liver Function Studies										
(CBC) Complete Blood Count										
(CEA) Carcinoembryonic Antigens										
Chest X-rays										
Skeletal surveys										
Bone scan										
Liver scan										

Surveillance Testing: Medical Oncologist

Date of visit	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Surveillance type										
Patient History										
Physical Exam										
Mammogram										
Liver Function Studies										
(CBC) Complete Blood Count										
(CEA) Carcinoembryonic Antigens										
Chest X-rays										
Skeletal surveys										
Bone scan										
Liver scan										

Surveillance Testing: GYN

Date of visit	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Surveillance type										
Patient History										
Physical Exam										
Mammogram										
Liver Function Studies										
(CBC) Complete Blood Count										
(CEA) Carcinoembryonic Antigens										
Chest X-rays										
Skeletal surveys										
Bone scan										
Liver scan										

1. Tumor Recurrence N Y → Local ☐
   Skin ☐
   Bone ☐
   Lung ☐
   Brain ☐
   Liver ☐

2. MD Type: Surgeon ☐ Radiation oncologist ☐ Medical oncologist ☐ Gynecologist ☐

3. Date of dx _____/_____/_____

4. How recurrence diagnosed: Test Positive (Y N)

Patient History	_____
Physical exam	_____
Mammogram	_____
LFT	_____
CBC	_____
CEA	_____
Chest Xray	_____
Skeletal surveys	_____
Bone scan	_____
Liver scan	_____

Has patient died N Y → Cause of death _____

Date of death _____/_____/_____